

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include changes to FIGS. 3, 10A, 10B and 11A. These sheets, which include FIGS. 3, 10A, 10B and 11A, replace the original sheets including FIGS. 3, 10A, 10B and 11A. FIGS. 3 and 11A were amended to correct drafting errors. In amended FIGS. 10A and 10B, reference number “168” has been changed to “184” as directed by the Examiner.

Attachment: Replacement Sheets
Annotated Sheets Showing Changes

REMARKS

Reconsideration of the application in view of the above amendments and the following remarks is requested.

Election/Restriction

Pursuant to a restriction requirement, Applicants hereby elect to prosecute the claims of Group I. Applicants withdraw claims 7, 8, 14, 15, 20, 31, 36, 39-53 and 73 as being directed to non-elected species, until generic claims are allowed. Applicants note that the Examiner did not address Applicants' comments regarding the heat exchanger arrangements (HE) and homogenizer species "H2". Applicants have cancelled claims 54-72 subject to Applicants' right to present these claims in a divisional application.

Amendments to the Claims

Claims 17, 18, 24 and 27 have been amended to clarify the present invention (*see below*) and correct obvious drafting errors.

New dependent claims 74-75 recite additional features disclosed in the Specification at page 34, line 10-17. See also, FIG. 13.

New dependent claims 76-77 recite additional features disclosed in the Specification at page 18, line 7-10 and page 34, lines 10-14. See also, FIG. 13.

New independent claim 78 and dependent claim 79 recite features disclosed in the Specification at page 35, line 7-14. See also, FIG. 13

No new matter has been added by the foregoing amendments.

Amendments to the Specification

The specification has been amended to conform to the amendments of FIGS. 10A and 10B and also to correct obvious drafting errors. No new matter has been added by these amendments.

Amendment to the Drawings

FIG. 3 has been amended to change the positioning of the line leading from the flow splitter 26 to the pressure relief valve 32 and conform FIG. 3 to FIGS. 11A and 13.

FIGS. 10A and 10B have been amended by changing element number "168" to element number "184" as directed by the Examiner.

FIG. 11A has been amended to correct drafting errors by deleting the element number 210 having a lead line going to a flow restrictor and renumbering it as element number 209. Also, the dotted line identifying the elements included in element 210 (processor assembly) has been amended to exclude ion exchange device 206. Support for these amendments can be found in the Specification at page 30, line 13 to 24.

No new matter has been added by the foregoing amendments.

Objections to Drawings

The drawings were objected to under 37 CFR 1.83(a) as not showing the spring-loaded adjustable pressure relief valve recited in claim 9. Applicants respectfully traverse this objection. Applicants direct the Examiner's attention to FIG. 13 showing pressure relief valve 391 (*See*, Specification, page 34, line 24). FIG. 3 also shows a pressure relief valve 32 (Specification, page 15, line 21-23) which is preferably an adjustable spring-loaded type pressure relief valve (Specification, page 16, line 20-24).

35 U.S.C. §112 Rejections

Claims 17, 18-22 and 24-30 were rejected under 35 U.S.C. §112, second paragraph. The Examiner stated that claims 24-30 would be allowable if rewritten to overcome the rejection.

With regard to claims 17 and 18, the Examiner stated that it was unclear how a temperature controller can control the temperature of the fluid without a reactor for heating the fluid and a heater for heating the reactor.

Claims 17 and 18 have been amended to replace the term “temperature controller” with the term “means for controlling the temperature of the fluid in the processor assembly”. Support for these amendments can be found in the Specification which describes that the means for controlling the temperature can be heaters or coolers and further, that the means for controlling the temperature may also include temperature controllers for controlling the heaters or coolers. Specification at: page 15, lines 16-20; page 18, line 14 to page 19, line 19; and page 33, line 22 to page 34, line 3.

Applicants submit that claims 17 and 18, as amended, overcome the rejection under 35 U.S.C. §112. Claims 19-22 depend from claim 18 and overcome the rejection under 35 U.S.C. §112 for the same reasons as claim 18.

With respect to claim 24, the Examiner stated that it was unclear as to how the process control system is connected to elements of the startup loop assembly. Applicants have amended claim 24 to clarify this connection. Support for this amendment can be found the Specification at page 31, line 10 to page 32, line 8 and FIGS. 10A-11B. Applicants submit that amended claim 24 overcomes the rejection under 35 U.S.C. §112. Claims 25-30 depend from claim 24 and overcome the rejection under 35 U.S.C. §112 for the same reason as claim 24.

35 U.S.C. §102 REJECTIONS

Claims 1-4, 10-13, and 16 were rejected under 35 U.S.C. 102(b) as being anticipated by U.K. Patent Application GB 2 002736A (“*Alhauser*”). Applicants respectfully traverse this ground of rejection. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP 2131, *citing, Verdegaa Bros. v. Union Oil*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). Further, although identity of terminology is not required, “[t]he elements must be arranged as required by the claim....” MPEP 2131, *citing, In re Bond*, 910 F.2d 831, 15 USPQ2d 1566. (Fed Cir. 1990) (emphasis added). As discussed in detail below, *Alhauser* fails to meet these requirements.

Independent claim 1 recites a “processor assembly for processing the fluid from the pump.” A preferred processor assembly is described in the specification as “any device or apparatus for processing a fluid, wherein control over the pressure, flow rate or temperature of the fluid being processed is important.” (Specification, page 15, lines 15-18). In contrast, in *Alhauser*, what the Examiner describes as a fluid processor is merely a reverse osmosis apparatus for “separating” pyrogens from water (*Alhauser* at page 1, lines 49-51, 91-96; page 2, lines 101-106.) Thus, reverse osmosis apparatus 56 of *Alhauser* is actually a “filter” and not a fluid processor as required by claim 1.

Alhauser also fails to disclose the claimed “pressure relief valve”. A preferred pressure relief valve is described in the specification as a valve “designed to open when the pressure of the fluid in the recirculating loop reaches a specified pressure and to close when the fluid pressure falls below the specified pressure.” (Specification, page 16, lines 21-23) In contrast, what the Examiner describes as a “pressure relief valve” in *Alhauser* is actually an “adjustable throttle 36” (*Alhauser*, page 2, line 90) for controlling the “quantity” of

concentrate departing from reverse osmosis apparatus 24 (*Alhauser*, page 2, line 129 *et seq.*).

Further, *Alhauser* does not disclose a flow splitter, first flow restrictor, second flow restrictor and pressure relief valve constructed and arranged to coact with each other to control the pressure and flow rate of the fluid in the fluid processor as recited in claim 1. The Examiner has provided no reference in *Alhauser* to support his assertion that this limitation is disclosed. In fact, *Alhauser's* disclosure is limited to setting throttles 36, 38 and 64 to control the quantity of concentrate departing reverse osmosis apparatuses 24 and 56 (*Alhauser* at page 2, line 129 to page 3, line 77).

Based on the foregoing, *Alhauser* fails to disclose all of the elements recited in independent claim 1 and therefore does not anticipate claim 1. Claims 2-4, 10-13 and 16 depend from claim 1 and are allowable over *Alhauser* for the same reason as claim 1.

In addition, as to dependent claim 2, the Examiner states that *Alhauser* discloses that the process control system maintains the pressure of the fluid in the processor assembly at least about the saturation point of the fluid at a predetermined temperature. However, nothing in *Alhauser* discloses that the pressure of the fluid in the reverse osmosis apparatus 56 (i.e., what the Examiner describes as a processor assembly) of the device of *Alhauser* is maintained at least about the saturation point of the fluid at a predetermined temperature as recited by claim 2.

In dependent claims 12 and 13, the Examiner states that *Alhauser* discloses a reverse osmosis device 24. Applicants respectfully disagree. The reverse osmosis device 24 of *Alhauser* was previously described by the Examiner as the flow splitter recited in claim 1 (*see*, Office Action at page 6.). Reverse osmosis device 24 of *Alhauser* cannot also be the reverse osmosis device recited in dependent claims 12 and 13.

Claims 1-4, 10-13, 16 and 23 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,072,610 ("*Gow*"). Applicants respectfully traverse this ground of rejection on the ground that *Gow* fails to disclose all of the limitations recited in independent claim 1.

Gow does not disclose a "pressure relief valve" disposed between a flow restrictor and flow splitter as recited in claim 1. The pressure relief valve 84 disclosed in *Gow* is used as part of a heat exchanger and is disposed between an inlet and a tank. (*Gow* at col. 5, line 14-16.) The Examiner asserts that valve 38 of *Gow* is a pressure relief valve. However, valve 38 is disposed between a return tank 26 and an outlet 38. (*Gow* at col. 4, lines 20-21 and FIG. 1.) Applicants also note that *Gow* specifically describes pressure relief valves as such. For example, "heat exchanger 34 also connects the inlet 80 to the tank 26 by way of a pressure relief valve 84." (*Gow* at col. 5, line 14-16.) If valve 38 were, in fact, a pressure relief valve, it would have been so described in the *Gow* reference.

The Examiner further asserts that *Gow* discloses that reverse osmosis filters 24, pressure responsive valve 30, pressurizing valve 60 and valve 38 of *Gow* (which the Examiner respectively describes as a flow splitter, first and second flow restrictors and pressure relief valve) are constructed and arranged to coact with each other to be capable of controlling the pressure and flow rate of the fluid in the fluid processor. However, the Examiner has not indicated where in *Gow* such disclosure is made.

Based on the foregoing, *Gow* does not disclose all of the elements recited in independent claim 1 and therefore does not anticipate claim 1. Claims 2-4, 10-13, 16 and 23 depend from claim 1 and are allowable over *Gow* for the same reasons.

Also, as to claim 2, the Examiner states that *Gow* discloses the process control system as "maintaining the pressure of the fluid in the processor assembly at least about the

saturation point of the fluid at a predetermined temperature (e.g., at a temperature of the main sterilizer).” (Office Action, page 8) Applicants respectfully disagree. *Gow* merely discloses that the pre-heater and main sterilizer of the device of *Gow* heats a solution to a particular temperature. (*Gow* at col. 4, line 41-68)

Finally, claim 13 recites a RODI apparatus (comprising a reverse osmosis device and an ion exchange device) disposed between the prefilter and the processor assembly No such apparatus is disclosed in *Gow*.

35 U.S.C. §103 Rejections

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.’ *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). ‘All words in a claim must be considered in judging the patentability of that claim against the prior art.’ *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)”
MPEP § 2143.03. See also: MPEP. § 2143 (“[T]he prior art reference (or references when combined) must teach or suggest all the claim limitations.”) The references cited by the Examiner fail to meet this requirement.

Dependent claims 5 and 6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Alhauser* in view of U.S. Patent No. 3,249,229 (“*Kasten*”) Applicants respectfully traverse this ground of rejection.

Claims 5 and 6 depend from independent claim 1 and are allowable over *Alhauser* for the reasons discussed above with respect to claim 1. *Kasten* is cited by the Examiner for disclosing a fixed setting flow restrictor in the form of a fixed length capillary type tube. However, the device disclosed in *Kasten* is not a fluid processor as recited in claim 1. Also, *Kasten* does not teach or suggest a processor assembly or a process control system as recited in

claim 1. Thus, the combination of *Alhauser* and *Kasten* does not yield the present invention or render claims 5 and 6 obvious.

Dependent claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Alhauser* in view of U.S. Patent No. 5,147,532 ("*Leek*"). Applicants respectfully traverse this ground of rejection. Claim 9 depends from independent claim 1 and is allowable over *Alhauser* for the reasons discussed above with respect to claim 1. Further, *Leek* does not disclose a "spring-loaded adjustable pressure relief valve" as recited in claim 9. A pressure relief valve is described in the Specification as a valve designed to open when the pressure of the fluid reaches a specified pressure and to close when the fluid pressure falls below the specified pressure. (Specification, page 16, lines 21-22.) In contrast, *Leek* disclosure is limited to a "spring loaded valve 61" which allows some water to wash the membrane of a reverse-osmosis filter and then to escape the filter. (*Leek*, col. 5, lines 11-14.) In addition, *Leek* does not teach or suggest a processor assembly or process control system recited in claim 1. Thus, the combination of *Alhauser* and *Kasten* does not yield the present invention or render claim 9 obvious.

Also, the Examiner stated that it would have been obvious to have modified the valve of *Alhauser* so as to have included the spring loaded valve disclosed in *Leek* in order to permit water to escape from the housing of the reverse osmosis filter to wash the membrane. However, this combination does not yield the invention. Claim 9 requires that the spring-loaded adjustable pressure relief valve, flow splitter and flow restrictors coact with each other to control the pressure and flow rate of the fluid in the fluid processor.

Claims 32-35, 37, and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Gow* as applied to claim 23, and further in view of U.S. Patent No. 1,027,831 ("*Fox*"). Applicants respectfully traverse this ground of rejection.

Claims 32-35, 37, and 38 depend from claims 23 and independent claim 1 and are, therefore, allowable over *Gow* for the same reasons discussed above with respect to claims 1 and 23.

In addition, as to claim 35, *Fox* does not teach or suggest that the heater and reactor are disposed within a “temperature homogenizer”. Instead, *Fox* discloses tubes 16 surrounded by electrical coils 17, wherein the tubes are disposed within the chamber of an annular-shaped boiler. What the Examiner describes as a temperature homogenizer 5, 12 and 15 are, respectively, the “inner boiler shell 5” of the boiler, a “dome 12” on top of the boiler and a “base head 15” connected to the dome 12 by the tubes. (*Fox*, page 1, lines 45-85).

Further, the purpose of the claimed temperature homogenizer is to maximize the heat transfer to the reactor by providing more well-contacted surfaces for heat transfer. At the same time, the temperature homogenizer also maximizes the stability of the temperature of the fluid within the reactor by acting as form of “thermal capacitor”, i.e., it protects the reactor from the effects of sudden heating or cooling. (See, Specification at page 30, lines 13-22. See also, FIGS. 5A and 5B.). In contrast, the tubes 16 and coils 17 of the device of *Fox* are exposed to the air flowing within the chamber 14 through air spaces. (*Fox* at page 1, lines 65-72) Thus, the inner boiler shell 5, dome 12, and base head 15 do not maximize heat transfer to the reactor by providing more well-contacted surfaces for heat transfer or protect the reactor from the effects of sudden heating or cooling.

As to claim 37, the Examiner states that *Fox* discloses a temperature homogenizer as including “a unitary structure 12 or 15 produced by casting ... the reactor 16 being an integral part of the homogenizer.” Applicants respectfully disagree. As discussed above with respect to claim 35, *Fox* does not teach or suggest a temperature homogenizer. Further, the inner boiler shell 5, dome 12, and base head 15 cannot be formed as unitary structure because inner boiler

shell 5 is part of an annular shaped boiler, which is a separate structure from dome 15 and base head 15. *Fox* also discloses that dome 15 is connected to the top of the boiler with lugs 13 to form air spaces that communicate with chamber 14 of the boiler. (*Fox*, page 1, lines 45-94) Thus, *Fox* teaches against forming the inner boiler shell 5, dome 12, and base head 15 as a unitary structure wherein the reactor is an integral part of the temperature homogenizer.

As to claim 38, the Examiner's assertion that *Fox* discloses a temperature homogenizer "enclosed by an insulation jacket 20" is incorrect. As previously discussed above, *Fox* does not teach or suggest a temperature homogenizer. Further, the purpose of the claimed jacket is to minimize the temperature homogenizer losing heat to ambient. (Specification, page 21, line 18 to page 22, line 2 and FIGS. 5A and 5B.) However, liner 20 of *Fox* is attached to an outer shell 19 which forms a chamber. Thus, liner 20 does not prevent the inner boiler shell 5, dome 12, and base head 15 from losing heat since the surfaces of the inner boiler shell, dome, and base head are exposed to air currents. See, *Fox* at FIG. 1

Claims 17-19, 21 and 22 were rejected under 35 U.S.C. 103 {a} as being unpatentable over *Gow* as applied to claim 23 and further in view of U.S. Patent Application Publication US 2002/0132341 A1 ("*Benedict*"). Applicants respectfully traverse this ground of rejection.

Amended claims 17-18 and claims 19, 21, 22 and 23 all depend from claim 1 and are therefore allowable over *Gow* for the same reasons discussed above with respect to claim 1. *Benedict* is cited by the Examiner for disclosing "that the use of [*process*] elements to automatically control and monitor a fluid treatment process is known in the art (see FIG, 1 and paragraphs 23 and 26)." However, *Benedict* does not disclose, teach or suggest a control system comprising: a flow splitter, a first flow restrictor, a pressure relief valve a second flow restrictor disposed downstream of the processor assembly wherein the flow splitter, first flow restrictor, second flow restrictor and pressure relief valve are constructed and arranged to coact with each

other to control the pressure and flow rate of the fluid in the fluid processor as recited in claim 1. Therefore, the combination of *Gow* and *Benedict* does not yield the present invention or render claims 17-19, 21 and 22 obvious.

Also, claims 21 and 22 recite a divert line. A divert line means a line along which the product fluid that is diverted from the product outlet flows. (Specification at page 35, line 23 to page 36, line 6 and FIG. 13.) No such limitation is taught or suggested in *Benedict* or *Gow*. The Examiner's assertion that *Gow* discloses a divert line 70 is not correct. What *Gow* discloses is a "solution outlet 70 ... connected to a bottling plant 72." (*Gow*, col. 3, line 51-53.) In other words, outlet 70 of *Gow* is a product outlet and not a divert line as recited in claims 21, 22.

Also, claim 21 recites that the flow sensor and conductivity cell are disposed downstream of the processor assembly along a divert line while claim 22 recites that the endotoxin sensor, flow sensor and conductivity cell are disposed along a divert line. None of these limitations are disclosed in *Gow* or *Benedict*.

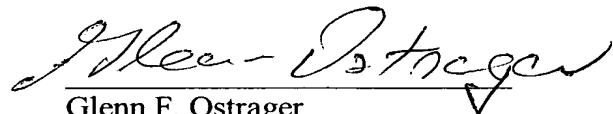
However, the Examiner states while *Benedict* fail to specify placing the flow sensor, conductivity cell, and endotoxin sensor along a divert line, such a modification would have been obvious in order to enable monitoring the quality of the finished product in the single pass treatment process of *Gow*. However, in order to establish a prima facie case of obviousness "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." MPEP § 2143. There is no suggestion or motivation in *Benedict* or *Gow* for the modification described by the Examiner. Further, the Examiner has not pointed out any suggestion or motivation in the knowledge generally available to one of ordinary skill in the art for said modification.

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On the basis of the above amendments and remarks reconsideration of this application
and its allowance are requested.

Respectfully submitted,

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Date



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ANNOTATED SHEET SHOWING CHANGES

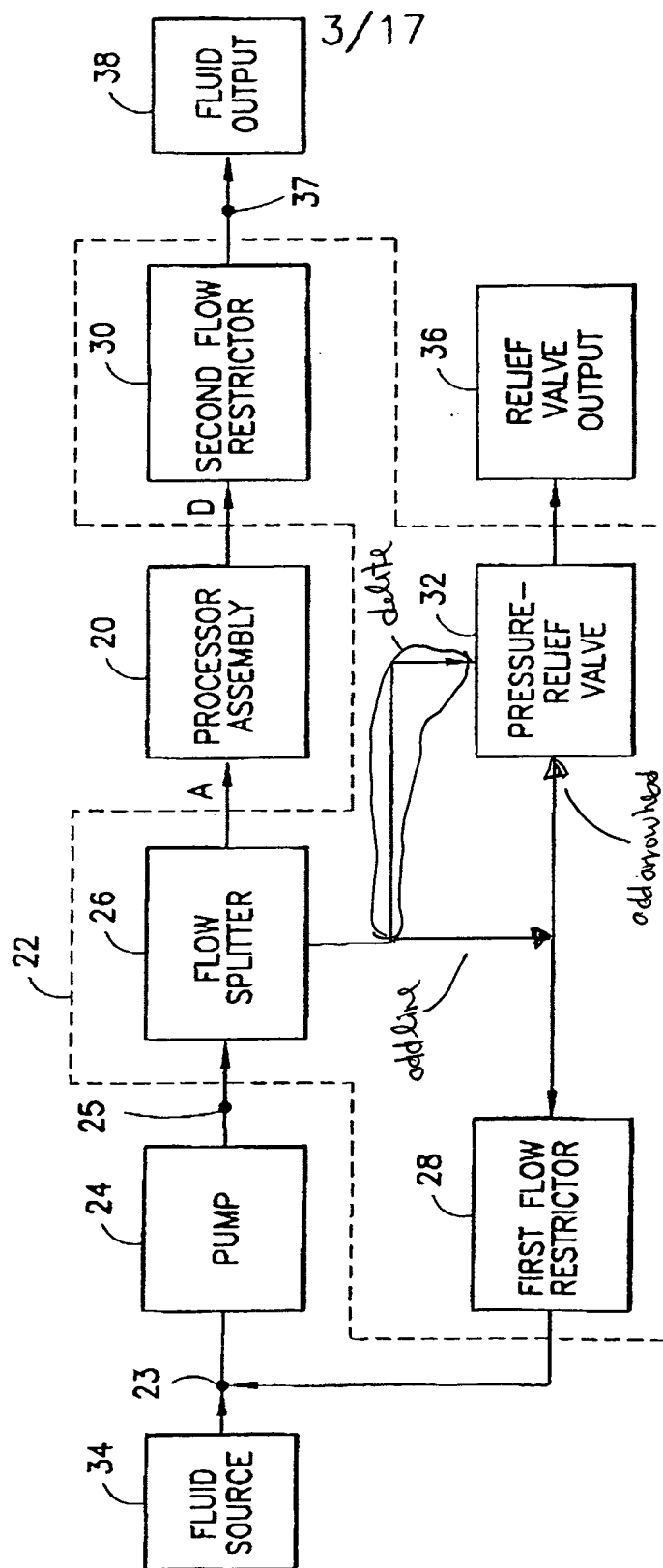


FIG.3

13/17

PROCESSOR ASSEMBLY

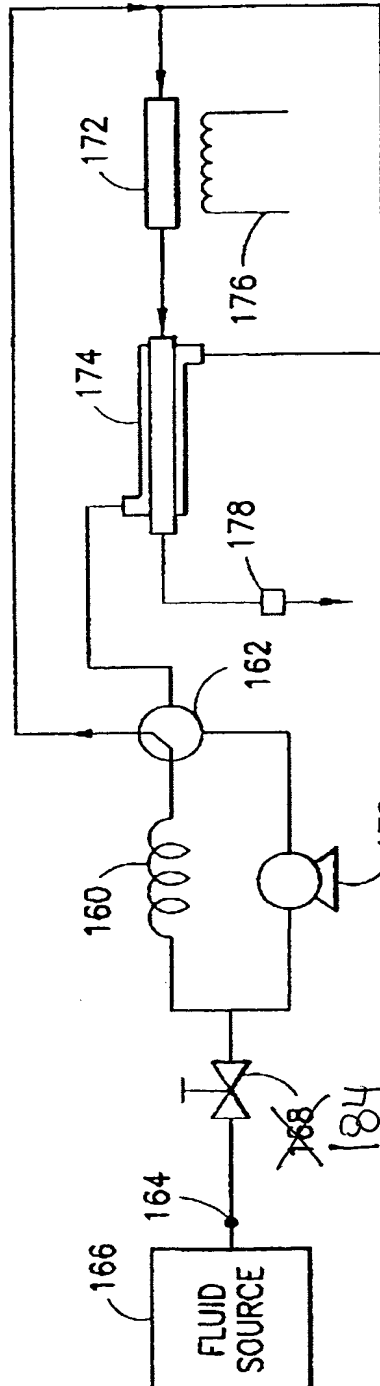


FIG. 10A

Re-number
168 to 184

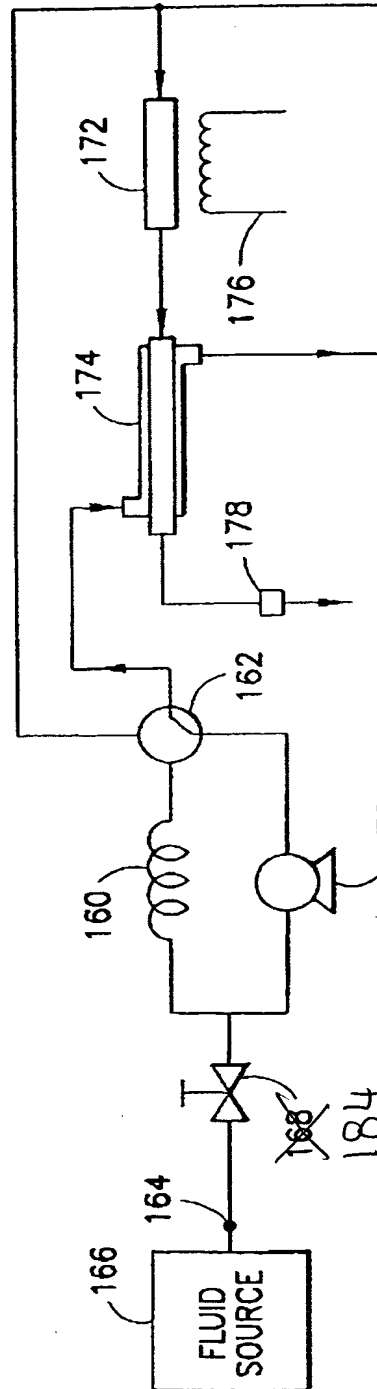


FIG. 10B

Re-number
168 to 184

14/17

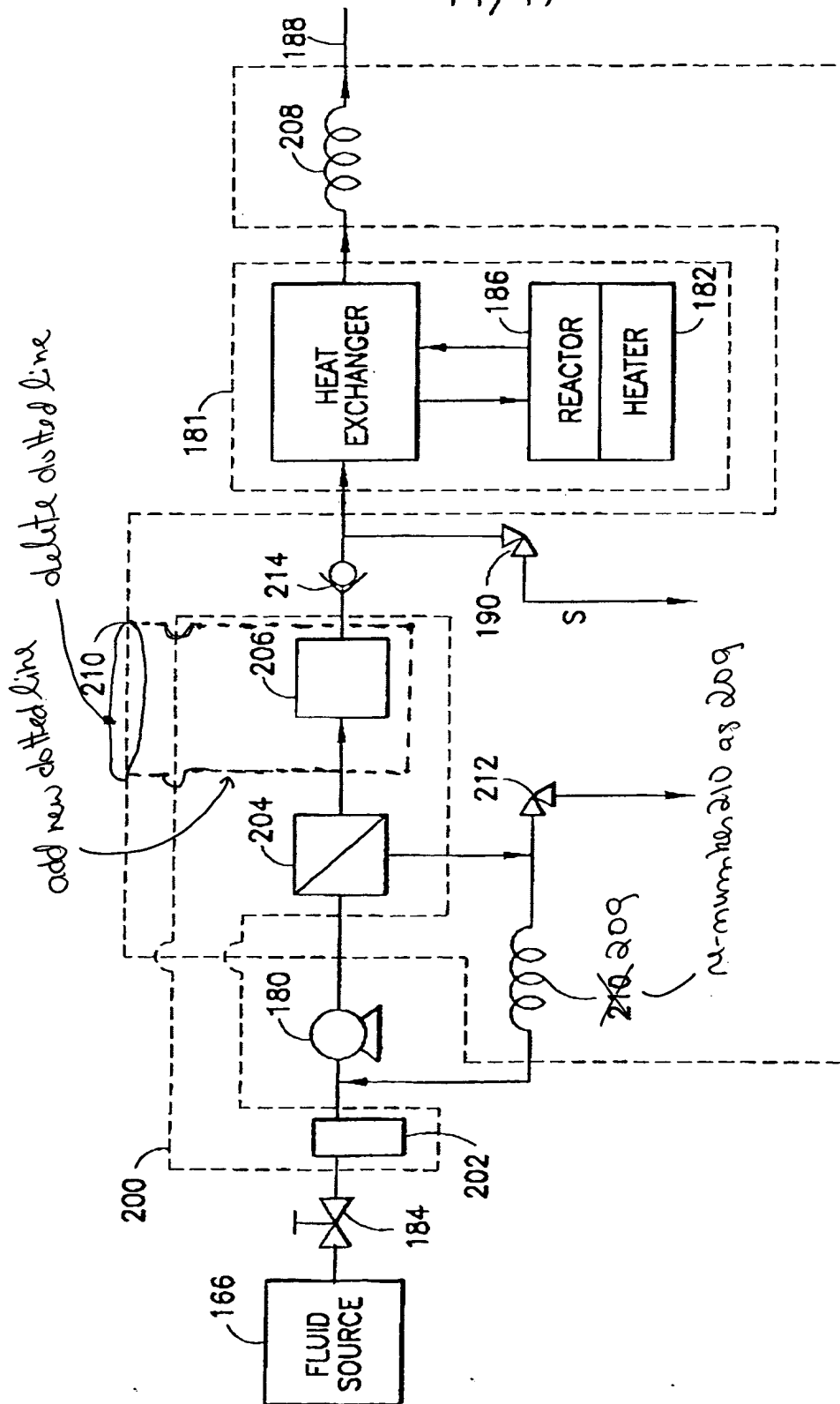


FIG.11A